

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

Institutional Review Boards:

Promising Approaches



**JUNE GIBBS BROWN
Inspector General**

**JUNE 1998
OEI-01-91-00191**

EXECUTIVE SUMMARY

PURPOSE

To identify promising approaches that institutional review boards use to enhance their effectiveness and efficiency in protecting human subjects.

BACKGROUND

Role of Institutional Review Boards

Institutional review boards (IRBs) play vital roles in protecting human research subjects. They review initial research plans to make certain that the plans provide subjects with adequate opportunity to provide informed consent and do not expose subjects to unreasonable risks. They also conduct continuing review of approved research to ensure that human-subject protections remain in force. They carry out their initial and continuing review functions in accord with Federal regulations first established in the 1970s and applicable to all research funded by the U.S. Department of Health and Human Services or carried out on products regulated by the Food and Drug Administration.

In carrying out their responsibilities, IRBs face challenges posed by a changing research environment. Advances in genetics research, a proliferation of large-scale trials, and the blurring definitions of research and therapy make research increasingly complex to review and oversee. Across the country IRBs are inundated with research plans and are under enormous pressure to review them quickly. At the same time, many are finding it difficult to recruit and maintain members. Despite these challenges, many IRBs have developed innovative strategies for reviewing research plans and for providing educational outreach. Yet, in this environment there is little time for the sharing of promising approaches among the thousands of IRBs in existence.

Promising Approaches: The Focus of this Report

This report focuses on promising approaches of IRBs. One of 4 reports we are issuing on IRBs, it draws on interviews and group discussions with representatives of about 75 IRBs; site visits to IRBs in 6 academic health centers where extensive clinical research is taking place; reviews of Federal records and pertinent literature; and attendance at IRB meetings.

The promising approaches included here address six key areas of responsibility for IRBs. Within each area, we have chosen promising approaches that seem to have potential for multiple IRBs. We recognize, however, that what works well in one IRB may not necessarily work well in another.

PROMISING APPROACHES

Managing the Workload

To reduce workload pressures, many institutions are creating multiple IRBs and/or increasing the number of IRB meetings. Some institutions are creating specialty IRBs, such as dental, medical or social science IRBs to ensure that board members have sufficient expertise to assess research plans. Other institutions maintain general-purpose IRBs but stagger their meetings. One IRB staggers its four board meetings so that there is an IRB meeting every week. A research investigator submitting a research plan to this IRB will have his or her plan reviewed by the first available board. The waiting period is generally no longer than one week.

Providing Educational Outreach to Research Investigators

To ensure that all research investigators receive minimal training about human-subject protections, some institutions require their research investigators to attend mandatory training programs. A dean at one institution will not sign off on approved research until investigators have attended a 2-day workshop. According to IRB staff, this method provides a powerful political message to all investigators about the importance of human-subject education. Another institution requires all of its investigators to complete an on-line tutorial about human-subject protections. This tutorial, which takes an hour to complete, provides a base level of education for a nominal fee to the institution.

Reviewing Approved Research

Using a third party to oversee research is an effective technique for IRBs that do not have the time to observe the research process themselves. One IRB requires a research intermediary to interact with all psychiatric patients involved in research projects. Among other things, the research intermediary discusses the consent form with patients after the form has been signed to ensure that upon reflection, patients continue to want to participate in the research. Every few months, the research intermediary reports to the IRB about patients' concerns and the ways in which the consent process and/or research could be made more efficient and less obtrusive for patients.

Providing Educational Outreach to IRB Members

Educating IRB members is an important strategy for ensuring that they have adequate expertise to assess research plans. One IRB sends its members literature relevant to the research plan being discussed. This approach has been particularly beneficial to help orient new members to the ethical issues they should consider when reviewing protocols. Another IRB devotes a portion of each meeting to education. A benefit of this type of education, according to the IRB director, is the ripple effect it can have with other researchers in the institution. For example, after a recent meeting where AIDS trials were discussed, two of the physician members shared the discussion with their residents.

Broadening Perspectives in the IRB Review Process

A strategy for providing thoughtful, fair review is to continually maintain contact with the community in which the research takes place. One IRB established an Office of Ethnic Diversity in Research to help it identify barriers the community faces when participating in research and potential strategies to overcome these barriers. For example, many in the community are unaware of what being a research subject entails and they associate the hospital with treatment rather than research. Through community outreach, the IRB has become sensitive to the need to further simplify consent forms in order to impress upon potential subjects that they are participating in research.

Evaluating IRB Effectiveness and Efficiency

To improve its operations, one IRB performed a two-pronged self-evaluation. First, it convened a group of faculty members to perform a month-long evaluation of its operations. Second, it hired an outside monitor to assess research protocols for regulatory compliance and to interview investigators about their interactions with the IRB and their experiences with the review process. Both evaluations were helpful in highlighting areas that needed improvement, such as increased resources for the IRB, changes in the reporting structure, and more support from the University. The resultant changes have also helped to create better relations between researchers and the IRB.

CONCLUSION

Despite the challenges posed by the new research environment, IRBs have employed many promising approaches to enhance their effectiveness and efficiency. A key challenge to the Federal government is to find ways of giving IRBs the flexibility to develop innovative approaches while at the same time holding them accountable for performance. This is a matter we address in our summary report entitled, *Institutional Review Boards: A Time For Reform*.

COMMENTS ON THE DRAFT REPORTS

Within the Department of Health and Human Services, we received comments on our four draft reports from the National Institutes of Health, the Food and Drug Administration and, jointly, from the Assistant Secretary for Planning and Evaluation and the Assistant Secretary for Health. We also solicited and received comments from the following external parties: the Applied Research Ethics National Association, the American Association of Medical Colleges, the Consortium of Independent Review Boards, and Public Citizen's Health Research Group. We include the detailed text of all of these comments and our responses to them in appendix D of our overview report, *Institutional Review Boards: A Time for Reform* (OEI-01-97-00193). In the executive summary of that report, we summarize the thrust of these comments and our responses.